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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/979,518

04/10/2002

Judith E Meis

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7590

07/03/2008

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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

07/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/979,518	Applicant(s) MEIS, JUDITH E	
	Examiner Richard G. Hutson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60,61,63,64,66 and 67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60,61,63,64,66 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's cancellation of claim 68-70 and amendment of claim, in the paper of 3/26/2008, is acknowledged. Claims 60, 61, 63, 64, 66 and 67 are present and at issue for examination.

Applicants' arguments filed on 3/26/2008, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Upon further consideration it has been decided that the following rejection based upon obviousness is deemed appropriate for the claims as they now exist. This has resulted in a non-final office action. Any inconvenience to applicants is sincerely regretted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 60, 61, 63, 64, 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roche Molecular Biochemicals Catalog, 1999, pages 50-51, See IDS, Sellman et al. Journal of Bacteriology, Vol 174, No. 13, pages 4350-4355, see IDS, July 1992, Lu et al. BioFeedback, Vol 11, No. 4, pages 464-466, 1991, See IDS.

Roche Molecular Biochemicals Catalog, 1999 teaches a one step RT-PCR System and methodologies comprising incubating RNA templates in a buffer solution containing dNTPs and one or more primers complementary to at least a portion of one or more of the RNA templates with a purified DNA polymerase from *Carboxydotherrnus hydrogenoformans* and a *Taq* DNA polymerase, in the presence of 12.5 mM Mg and in the substantial absence of Manganese. Roche Molecular Biochemicals Catalog, 1999 further teach that while other thermoactive DNA polymerase with reverse transcriptase activity use manganese ions as co-factors, manganese has a negative effect on the fidelity of DNA synthesis

Sellman et al. teach the purification and characterization of DNA polymerase from various species of Bacillus. Spellman et al. specifically teach the DNA polymerase enzymes from Bacillus Stearothermophilus require Mg²⁺ for optimal activity (See abstract). Sellman et al. also teach that the Bst DNA polymerase had its greatest activity at a concentration of magnesium of 10mM and that the addition of more magnesium did not result in a significant increase in polymerase activity.

Lu et al. teach that subtilisin digestion of the Bst polymerase I holoenzyme results in a large fragment that results in the same uniform DNA synthesis as the original full-length enzyme and that this fragment is stable at ambient temperature.

One of skill in the art at the time of the invention would have been motivated to practice methods similar to those taught by the Roche Molecular Biochemicals Catalog, 1999, with the exception of replacing the purified DNA polymerase from *Carboxydotherrnus hydrogenoformans* and *Taq* DNA polymerase with the DNA

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polymerase from *Bacillus stearothermophilus* as taught by either Sellman et al. or Lu et al. in order to convert a RNA template to a cDNA template and amplify the synthesized cDNA via a polymerase chain reaction. The expectation of success is high based upon the similar methods taught by Sellman et al. and those taught by Lu et al. who teach similar DNA synthetic reactions using Bst DNA polymerase. Further given the results of Sellman et al. Lu et al. and Roche Molecular Biochemicals Catalog, 1999, the substitution of the Bst DNA polymerases taught by Sellman et al. or Lu et al. into the methods taught by Roche Molecular Biochemicals Catalog, 1999 would yield predictable results.

Thus claims 60, 61, 63, 64, 66 and 67 are obvious over Roche Molecular Biochemicals Catalog, 1999, Sellman et al. and Lu et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rg
7/1/2008

/Richard G Hutson, Ph.D./
Primary Examiner, Art Unit 1652